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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,375	09/25/2003	Cang Lam	31150-1170 (USGI-005 CIP	8551
20350	7590	09/05/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,375

Applicant(s)

LAM ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/29/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14 and 16-21 is/are rejected.
- 7) ☒ Claim(s) 13, 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/04, 6/05, 7/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayhurst et al. (5,269,809). Hayhurst et al. disclose, at least in figures 1-3, 6-9, and 11-12B, an apparatus for securing a tissue fold within a patient, where the apparatus includes an anchor assembly (e.g., see fig. 8) having proximal (74) and distal (12) anchors connected by a suture (20), where the anchor assembly is adapted for adjustment of the length of suture between the anchors, where the anchor assembly is adapted of unidirectional (by movement of 74 toward 70) and bi-directional (by also changing the location of knot 22) adjustments of the length of suture, where the proximal anchor is adapted for adjustment of the length of suture between the proximal and distal anchors, where the proximal anchor comprises an adjustment mechanism (74 and 70), where the distal anchor is substantially fixed with respect to the suture; where the adjustment mechanism comprises a one-way valve (at 74), a slipknot (22) formed near the distal end of the suture, and an inclined plane (at 76 or 72); and where the apparatus includes

an anchor delivery system (28). Note: The introductory statement of intended use ("for securing a tissue fold within a patient") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Hayhurst et al., which is capable of being used as claimed if one desires to do so.

3. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanstrom et al. (6,669,707). Swanstrom et al. disclose, at least in figures 28-30 and in col. 15, line 39 to col. 16, line 11; an apparatus for securing a tissue fold within a patient, where the apparatus includes an anchor assembly (86) having proximal (wound 89') and distal (88') anchors connected by a suture (89'), where the anchor assembly is adapted for adjustment of the length of suture between the anchors, and where the apparatus includes an anchor delivery system ("hollow needle or trocar"). Note: The introductory statement of intended use ("for securing a tissue fold within a patient") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Swanstrom et al., which is capable of being used as claimed if one desires to do so.

4. Claims 1, 8, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Laufer et al. (6,494,888). Laufer et al. disclose, at least in figures 2-10, an apparatus for securing a tissue fold within a patient, where the apparatus includes an anchor assembly (730) having proximal (732) and distal (734) anchors connected by a suture (822), where the anchor assembly is adapted for adjustment of the length of suture

between the anchors (by adjustment of the location of knot 823), and where the apparatus includes an anchor delivery system (700) and plication apparatus (740).

5. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Cope (6,699,263). Cope discloses, at least in fig. 9, an adjustable anchor assembly including proximal (63) and distal (64) anchors and a length of suture (65) disposed between the anchors, where the anchor assembly is adapted for adjustment of the length of the suture while the anchor assembly is disposed within the patient. Note: The introductory statement of intended use ("for securing a tissue fold within a patient") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Cope, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 9-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanstrom et al (6,669,707) in view of Cope (6,699,263). Swanstrom et al. disclose the invention substantially as claimed. Swanstrom et al. disclose, at least in figures 5-7 and 11, an apparatus with an anchor delivery system including a needle (e.g. 17) and a pushrod (20), but do not disclose a flexible delivery tube that includes a proximal anchor. Cope teaches, at least in col. 4, line 17-60, a catheter (50) or flexible delivery tube for an anchor delivery system that includes a proximal anchor. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Cope, to include a flexible delivery tube that includes a proximal anchor in the apparatus of Swanstrom et al. Such a tube would allow delivery of anchors to internal tissues located deep within a patient's body or hollow organs.
8. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cope (6,699,263) in view of Harrison et al. (5,403,326). Cope discloses, at least in figures 6-8, a method for securing gastrointestinal tissue (11 and 13) substantially as claimed, but does not disclose that the tissue is folded, and that a tissue fold is formed with a plication apparatus. Harrison teaches, at least in figures 5-8D, apparatuses and methods for securing a gastrointestinal tissue fold, including a plication apparatus (e.g., 40). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Harrison et al., to apply the method of Cope to securing a gastrointestinal tissue fold, and to apply a plication apparatus to form the fold. The method of Cope would allow fundoplication of the stomach with an anchor assembly

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that can be adjusted according to the size of tissue to be folded; while a plication apparatus would allow manipulation of tissue to be secured with the anchor assembly.

Allowable Subject Matter

9. Claims 13 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an apparatus including, inter alia, an anchor assembly with proximal and distal anchors and a length of suture between the anchors, an anchor delivery system including a flexible delivery tube, a needle, and an anchor tube coupled to a distal region of the flexible delivery tube; and an anchor pushrod adapted to reversibly trap the suture.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

August 30, 2006